

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **KALETRA**®

lopinavir / ritonavir oral solution

This Patient Medication Information is written for the person who will be taking **KALETRA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **KALETRA**, talk to a healthcare professional.

If your child is taking **KALETRA**, all of the information in this Patient Medication Information applies to them. As their caregiver, please read this information before they start taking **KALETRA**. Talk to your child's healthcare professional if you need any additional information on their condition and treatment.

Serious warnings and precautions box

KALETRA can cause **pancreatitis** (inflammation of the pancreas).

Tell your doctor if you develop symptoms, such as:

- abdominal pain
- nausea
- vomiting

These may be signs of **pancreatitis**. Your doctor must decide if these are related to pancreatitis and what to do about them.

What KALETRA is used for:

- the treatment of HIV (Human Immunodeficiency Virus) Infection
- HIV is the virus that causes Acquired Human Immunodeficiency Syndrome (AIDS)
- it is used in adults and children 6 months of age or older
- it is used along other medicines to treat HIV infection

How KALETRA works:

- KALETRA works by stopping the HIV virus from multiplying. This will help lower the amount of HIV in your body and keep it at a low level.
- KALETRA is not a cure for the HIV infection or AIDS. You can still get infections or other serious illnesses associated with HIV infection or AIDS.

- KALETRA does not reduce the risk of passing HIV to others with sexual contact or blood contamination. You should use appropriate precautions, such as practicing safe sex and not reusing or sharing needles.

The ingredients in KALETRA are:

Medicinal ingredients: lopinavir and ritonavir

Non-medicinal ingredients: KALETRA oral solution also contains acesulfame potassium, alcohol, artificial cotton candy flavour, citric acid, glycerine, high fructose corn syrup, Magnasweet-110 flavour, menthol, natural and artificial vanilla flavour, peppermint oil, polyoxyl 40 hydrogenated castor oil, povidone, propylene glycol, saccharin sodium, sodium chloride, sodium citrate, and water.

KALETRA comes in the following dosage forms:

As an oral solution. Each mL of KALETRA contains 80 mg of lopinavir and 20 mg of ritonavir.

Do not use KALETRA if:

- you are allergic to lopinavir, ritonavir or to any of the ingredients in KALETRA.

Do not use KALETRA if you are currently taking any of the following medicines. Taking KALETRA with these can cause serious problems and death:

- alfuzosin, used to treat high blood pressure
- apalutamide, used for prostate cancer
- astemizole and terfenadine, used to relieve allergy symptoms
- carbamazepine, phenytoin and phenobarbital, used as anticonvulsants
- cisapride, used to relieve certain stomach problems
- colchicine, when used in patients with kidney and/or liver problem, used to treat gout
- dronedarone, used to correct heart rhythm
- elbasvir / grazoprevir, used to treat hepatitis C virus infection
- efavirenz, nevirapine and nelfinavir – used to treat HIV
- ergotamine, dihydroergotamine (used to treat headaches), ergonovine, methylergonovine (used after labour and delivery)
- fusidic acid, used as an antibiotic
- lurasidone and pimozide, used to treat mental health problems
- neratinib, used to treat breast cancer
- triazolam and oral midazolam, used to relieve anxiety and trouble sleeping
- ranolazine, used to treat chronic angina (chest pain)

- rifampin, used to treat tuberculosis
- St. John's Wort (*Hypericum perforatum*), an herbal product used to treat depression
- lovastatin, lomitapide or simvastatin, used to lower cholesterol
- PDE5 inhibitors vardenafil, used to treat erectile dysfunction and pulmonary arterial hypertension (PAH), or sildenafil, used for the treatment of PAH
- salmeterol, used for asthma and chronic obstructive pulmonary disease
- venetoclax at the dose initiation and during the ramp-up phase, used to treat chronic lymphocytic leukemia

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take KALETRA. Talk about any health conditions or problems you may have, including if you:

- have liver problems.
- are infected with hepatitis B or hepatitis C. If you have liver disease, such as hepatitis B and hepatitis C, taking KALETRA may worsen your liver disease.
- have diabetes or symptoms, such as frequent urination and/or increase in thirst.
- have hemophilia, since KALETRA can increase bleeding in these patients.
- have heart disease or a heart condition, including conditions of Congenital Long QT Syndrome.
- have low potassium levels in your blood.
- have hereditary fructose intolerance since the KALETRA oral solution contains fructose.
- have kidney problems or inability to metabolize propylene glycol (such as in patients of Asian origin) as the KALETRA oral solution contains propylene glycol.
- suffer from alcoholism, epilepsy or brain injury, as the KALETRA oral solution contains alcohol.
- have been told you have high triglyceride levels in your blood.
- have had a condition called pancreatitis in the past.

Other warnings you should know about:

Pregnancy

Tell your doctor if you are pregnant or planning to become pregnant. It is not known if KALETRA can harm your unborn baby. Tell your doctor if you become pregnant while you are taking KALETRA. The KALETRA oral solution should not be used during pregnancy since it contains alcohol and propylene glycol.

Pregnancy Registry

There is a pregnancy registry for women who take antiretroviral medicines while they are pregnant. The purpose of this registry is to collect information about the health of you and your baby. If you do become pregnant while taking KALETRA, talk to your doctor about taking part in this registry.

Breastfeeding

You should not breastfeed if you are taking KALETRA. You should also not breastfeed a baby if you are infected with HIV. This is because you can pass HIV to your baby.

Severe Liver Problems

Severe liver problems, including deaths, have been reported in those using KALETRA. This has often occurred in those with advanced HIV disease, other liver disease or those taking many medications. There is no proven link to KALETRA use. Symptoms of serious liver problems include yellow skin and whites of eyes, nausea, tiredness, loss of appetite, fever, skin rash, pain in the upper abdomen, pale stools, and dark-coloured urine. Talk to your doctor if you get any of these symptoms.

Contraception

If you are taking oral contraceptives (“the pill”) or the contraceptive patch (i.e., ethinyl estradiol) to prevent pregnancy, you should use a different type of contraception since KALETRA may reduce the effectiveness of oral or patch contraceptives.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

The following medicines should only be used together with KALETRA if advised by your physician.

The following may interact with KALETRA:

- medicines used to treat erectile dysfunction, such as tadalafil, sildenafil and avanafil. Avanafil should not be taken with KALETRA as no safe and effective dose adjustment can be made.
- medicines used to treat pulmonary arterial hypertension, such as bosentan or tadalafil
- medicines used to lower blood cholesterol, such as rosuvastatin and atorvastatin
- some medicines affecting the immune system, such as cyclosporin, sirolimus and tacrolimus
- some medicines used to treat seasonal allergies and ear and eye infections, such as dexamethasone, fluticasone propionate and triamcinolone
- medicines used to treat asthma, such as budesonide
- contraceptives used to prevent pregnancy (e.g., ethinyl estradiol)
- medicines used to treat AIDS and related infections, such as amprenavir, fosamprenavir, indinavir, saquinavir, didanosine, tenofovir, maraviroc, rifabutin, etravirine, rilpivirine, tipranavir when used with low-dose ritonavir

- medicines used to treat HCV and related infections, such as telaprevir, boceprevir, glecaprevir/pibrentasvir, sofosbuvir/velpatasvir/voxilaprevir, simeprevir and ombitasvir/paritaprevir/ritonavir with or without dasabuvir
- medicines used to treat depression, such as trazodone and bupropion
- certain heart medicines, such as calcium channel antagonists including felodipine, nifedipine and nicardipine
- medicines used to correct heart rhythm, such as amiodarone, flecainide, bepridil, systemic lidocaine, propafenone hydrochloride, quinidine, and digoxin
- antifungals, such as ketoconazole, itraconazole and voriconazole
- morphine-like medicines used to treat severe pain, such as methadone
- anticonvulsants, such as lamotrigine and valproate
- anticoagulants, such as warfarin or rivaroxaban
- certain antibiotics, such as clarithromycin
- antibiotics used in the treatment of tuberculosis, such as delamanid and bedaquiline
- medicines used to treat cancer, such as abemaciclib, dasatinib, encorafenib, ibrutinib, ivosidenib, nilotinib, vincristine and vinblastine, as KALETRA may increase the concentrations of these drugs and increase adverse effects
- medicines used for low blood platelet count, such as fostamatinib
- fentanyl, used to treat pain in all forms, as this interaction may reduce breathing
- quetiapine, used to treat schizophrenia, bipolar disorder, and major depressive disorder
- medicines used to treat pain associated with endometriosis, such as elagolix

How to take KALETRA:

- Take KALETRA exactly as your doctor tells you to.
- Do not change your dose or stop taking KALETRA without talking to your doctor.
- You must stay under your doctor's care when taking KALETRA.

Usual dose:

- Your doctor will tell you how much KALETRA you should take and when you should take it.
- KALETRA is always taken along with other medicines used to treat HIV infection.
- The usual dose for adults is 5 mL of the oral solution twice a day.
- It may also be given as 10 mL of the oral solution once a day in some patients.
- For children aged 6 months to 18 years, the dose they are given will be based on their height and weight.

- KALETRA is always given twice a day for children.
- You must take the KALETRA oral solution with food.

Overdose:

KALETRA oral solution contains 42% alcohol and 15% propylene glycol and accidental ingestion could be toxic and could kill a young child. Keep KALETRA and all other medicines out of the reach and sight of children.

If you think you, or a person you are caring for, have taken too much KALETRA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you missed a dose of this medication, it should be taken as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not take 2 doses at the same time.

Possible side effects from using KALETRA:

These are not all the possible side effects you may feel when taking KALETRA. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Diarrhea
- Feeling weak or tired
- Headache
- Rash
- Some patients have large increases in triglycerides and cholesterol (forms of fat that are found in your blood).

Changes to your immune system (Immune Reconstitution Inflammatory Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time.

Autoimmune disorders (when the immune system attacks healthy body tissue) may also occur after you start taking medicines for HIV infection. Examples of this include: **Grave's disease** (which affects the thyroid gland), **Guillain-Barré syndrome** (which affects the nervous system), **polymyositis** (which affects the muscles), or **autoimmune hepatitis** (which affects the liver). Autoimmune disorders may occur at any time, even many months after the start of treatment.

If you are experiencing new symptoms, call your doctor immediately, for example:

- high temperature (fever), redness, rash or swelling
- fatigue
- joint or muscle pain
- numbness, tingling, or weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations (chest pain) or rapid heart rate
- yellowing of the skin or eyes
- anxiety and irritability accompanied by tremor of your hands or fingers
- muscle weakness in your hips, thighs, shoulders, upper arms, and neck

Your doctor may monitor blood levels of fats (lipids), cholesterol and glucose before and during KALETRA treatment.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Neuropathy and peripheral neuropathy: tingling feeling in hands, feet and around lips	✓		
Uncommon			
Chest pain		✓	
Pancreatitis (inflammation of the pancreas): abdominal pain, nausea and vomiting		✓	
Severe liver problems: yellow skin and whites of eyes, nausea, tiredness, loss of appetite, fever, skin rash, pain in the upper abdomen, pale stools, dark-coloured urine		✓	
Diabetes and high blood sugar: increased thirst, frequent urination		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 2 and 8°C in a refrigerator. If you keep KALETRA outside of a refrigerator, do not store above 25°C and discard any unused contents after 42 days (6 weeks). Avoid exposure to excessive heat. Keep cap tightly closed.

Keep KALETRA in the original package. Do not transfer to any other container.

Do not use after the expiry date on the package.

Keep out of reach and sight of children.

If you want more information about KALETRA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](#)); the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

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Date of Authorization: 2026-07-14

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